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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,596	08/19/2003	Choo Yuen May	3587-0110P	2776
2292 7590 07/13/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER CLARK, AMY LYNN	
			ART UNIT 1655	PAPER NUMBER
			NOTIFICATION DATE 07/13/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/642,596

Applicant(s)

MAY ET AL.

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,9,11,12 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) 8, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9 and 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/15/2006;10/19/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 October 2006 has been entered. Please note that this request was also acknowledged in the first requirement for election/restriction mailed out on 6 December 2006.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1, 8, 9 and 14-22 in the response filed on 5 January 2007 (please see the response to this election/restriction mailed out on 03/26/2007, which also provided an additional election/restriction requirement) and of Specie B, claims 1, 9, 11, 14, 16, 17 and 19-22 in the reply filed on 24 April 2007 is acknowledged. Please note that Applicant's amendments to claim 15 now makes claim 15 dependent upon claim 14, which is a generic claim, and Applicant's amendments to claim 18 now makes this claim dependent upon claim 17, which is also a generic claim. These amendments now provide further limitations on previously elected claims and are no longer alternative methods and restrictable based upon the way these claims now read, therefore, these claims are now under examination. The traversal of the restriction requirement between claim 8 and claim 21

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is on the ground(s) that claims 8 and 21 do not describe alternatives for carrying out the same step, wherein the step recited in claim 8 provides a definition on the preferred conditions for obtaining phytosterols, while the step recited in claim 21 provides definition on the preferred conditions for partitioning vitamin E and squalene after obtaining phytosterols. This is not found persuasive because claim 8 is drawn to a method of mixing the unsaponifiable matter with hydrocarbon solvent and claim 21 is drawn to a method of drying the mixture left after separation of the crystallized phytosterols and subsequently mixing it with hydrocarbon solvent. Since it appears the unsaponifiable matter and the mixture left after separation of the crystallized phytosterols are one and the same starting solution, it appears that these are different method steps applied to the same starting material.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 8, 11 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 24 April 2007.

Claims 1, 9 and 14-22 are currently under examination.

Response to Arguments

Information Disclosure Statement

The information disclosure statements (IDS) were submitted on 03/15/2006 and 10/19/2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Please note that only one reference has only had its abstract considered (Reference BE: EP 0 541 99-A1) because Applicant only supplied a translation of the abstract into English.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments, see "Applicant Arguments/Remarks Made in an Amendment", filed 19 October 2006, with respect to the rejection of claims 1-12 under 35 U.S.C. 103(a) as being unpatentable over Kirschenbauer (A*, US Patent 2,598,269), Jacobs (B*, US Patent 6,838,104) and Robinson et al. (C*, 6,057,462) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection of claims 1, 9 and 14-22 under 35 U.S.C. 103(a) as being unpatentable over Fizet (D, US Patent Number 5,487,817), in view of Willging (E, US Patent Number 4,550,183), Hattori (N, WO 01/32682 A1) and Hirata et al. (O, JP 09-176507 A, Translation provided herein).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9 and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fizet (D, US Patent Number 5,487,817), in view of Willging (E, US Patent Number 4,550,183), Hattori (N, WO 01/32682 A1) and Hirata et al. (O, JP 09-176507 A, Translation provided herein).

Fizet teaches a method of recovering tocopherols (Vitamin E) and sterols (please note that phytosterols are simply sterols obtained from plants, and these sterols are obtained from palm, which is a plant, these sterols are phytosterols) from vegetable sources, such as palm oil, comprising the steps of esterifying the sterols and fatty acids within the palm oil, distilling the resulting mixture to obtain residual fatty acids and, subsequently, obtain tocopherols, whereby the sterol esters formed in the esterification process remain in the residue of the distillation and the tocopherols are isolated from the distillate and the sterols, after cleavage of their esters, are isolated from the distillation residue (See abstract and column 2, lines 18-22). Fizet further teaches that the first distillation may be carried out at about 0.1 mbar of pressure and at a

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temperature of about 120 °C to about 150 °C with a short-path evaporator and that the distillation conditions can be varied based upon the content of the apparatus, the size and type of apparatus (See column 3, lines 66 and 67, continued into column 4, lines 1-6). Fizet further teaches that after further distillation, there is a distillation fraction (The second distillation fraction) that has a much higher content of tocopherols and that the second distillation may be carried out at a temperature range from 200 to about 220 °C. Fizet further teaches that the remaining acidic components, such as fatty acids and squalene, may be removed according to various methods in order to achieve a greater amount of tocopherols in the distillate and that the esterification is carried out in methanol in a temperature range from about 65 °C to about 100 °C (See column 4, lines 39). Fizet further teaches that the distillate may be treated with calcium hydroxide in the presence of water in an inert, water-miscible organic solvents, especially a lower alkanol such as isopropanol, which reads on saponification (See column 4, lines 40-49). Fizet further teaches that the sterols may be crystallized (See "Example 7", column 10, lines 13-18).

Willging teaches a method of obtaining purified tocopherols from palm oil (See abstract, column 2, lines 58-68, continued onto column 3, lines 1-3) comprising the step of extracting tocopherols with caustic methanol. Willging further teaches that water may be present with the caustic methanol and forms a tocopherol-enriched aqueous caustic methanol phase and a second phase containing organic impurities. Willging further teaches that the organic material that includes the impurities, wherein the impurities further contain squalene, waxes and sterols, and is substantially immiscible with the

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caustic methanol phase and can be separated from the tocopherol-enriched caustic methanol phase (See column 2, lines 1-27). Willging further teaches that an aliphatic hydrocarbon solvent, such as hexane, aids in the extraction of tocopherols and that the aliphatic hydrocarbon solvent must be used in a sufficient amount to maintain a two phase system and may be used whether or not an aliphatic hydrocarbon solvent was used in the initial extraction and may be added before, during or after the addition of the aqueous or non-aqueous neutralizing acid or the water (See column 3, lines 4-15 and 39-565 and column 7, lines 46-52). Willging further teaches that the purified tocopherol solvated in the neutralized methanol phase may be recovered from the methanol phase by distillation and that the water can also be distilled or separated as a separate phase after distillation of the methanol (See column 3, lines 54-67). Willging further teaches that an alternative method to distillation is phase separation (See column 4, lines 13-67).

Hattori teaches a method for producing a highly pure phytosterol by treating a crude fatty acid extract derived from a vegetable fat and/or oil, such as palm oil or palm kernel oil (See page 4), wherein the invention provides a process for distilling a raw fatty acid methyl ester to obtain a distillate and a residue. Hattori further teaches that a crude fatty acid ester may be obtained by esterifying a deodorized distillate of palm oil, which may be transesterified (See pages 4 and 5). Hattori further teaches that crystallization is carried out by adding water to the mixture of the crude fatty acid ester and the organic solvent (methanol). Hattori further teaches that the solution may be separated into phases in order to separate a lower phase comprising water/methanol,

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extracting and removing the lower phase, and then separating crystals (See page 7). Hattori further teaches a specific example using palm kernel oil, wherein the residue was added to methanol and potassium hydroxide, wherein a transesterification reaction was carried out, providing a crude fatty acid methyl ester product containing methyl esters of fatty acids and phytosterols and water was then added to the solution after the reaction and the solution was kept at 5 °C and crystallization was carried out. The precipitated crystals were recovered using a vacuum filter. Hattori further teaches that methanol was added to the crystals and they were dissolved in methanol and recrystallized (See page 11, "Example 1").

Hirata teaches a method of obtaining squalene from palm oil comprising mixing a vegetable oil and fat containing squalene, or a deacidified and deodorized distillate thereof, with an organic solvent (See abstract). Hirata further teaches that squalene is obtained as a distillate along with other unsaponifiable components, such as hydrocarbons, sterols, and tocopherol (See paragraphs 0005 and 0007). Hirata further teaches that a vegetable squalene concentrate can be manufactured by carrying out hydrogenation of a deacidified and deodorized distillate of palm oil by removing an impurity and condensing squalene (See paragraph 0010), however, the method provides a greater amount of squalene recovered if urea or thiourea is used (See paragraph 0012). Hirata further teaches that a ketone system, alcoholic system and hydrocarbon system, can be used as an organic solvent, although alcohol is desired (C₁-C₄).

The teachings of Fizet, Willging, Hattori and Hirata are set forth above. Fizet does not teach solvent partitioning of vitamin E and squalene, wherein the ratio of hydrocarbon solvent to short chain alcohol used to partition squalene and vitamin E is 5:3, nor does Fizet teach portioning squalene into hexane and vitamin E into methanol, nor does Fizet teach three stage short path distillation steps, nor does Fizet teach the exact temperatures and pressures claimed by Applicant. However, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the method taught by Fizet to provide the instantly claimed invention because at the time the invention was made, a method of recovering tocopherols and sterols from vegetable sources, such as palm oil, comprising the steps of esterifying the sterols and fatty acids within the palm oil, distilling the resulting mixture multiple times via short path distillation, wherein the distillation is first carried out at 0.1 mbar of pressure and at a temperature of about 120 °C to about 150 °C and that the distillation conditions can be varied based upon the content of the apparatus, the size and type of apparatus and wherein the second distillation may be carried out at a temperature range from 200 to about 220 °C, next saponifying the distillates to obtain tocopherols as one product and sterols as another product, wherein the sterols may be obtained through crystallization was known, as clearly taught by Fizet, as was a method of obtaining purified tocopherols from palm oil comprising the step of extracting tocopherols with caustic methanol, hexane, and optionally water may be present and forms a tocopherol-enriched aqueous caustic methanol phase to provide a bi-phasic system comprising

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tocopherol in one phase and organic compounds, such as squalene, waxes and sterols in the second phase, and wherein the two phases may be separated via phase separation or distillation or a combination thereof, as clearly taught by Willging, as was a method for producing a highly pure phytosterol by esterifying a deodorized distillate of palm oil, which may be transesterified, and further crystallizing the distillate, wherein crystallization is carried out by adding water to the mixture of the crude fatty acid ester and the organic solvent (methanol) and that the solution may be separated into phases in order to separate a lower phase comprising water/methanol, extracting and removing the lower phase, and then separating crystals, as clearly taught by Hattori, as was a method of obtaining squalene from palm oil comprising mixing a vegetable oil and fat containing squalene, or a deacidified and deodorized distillate thereof, with an organic solvent by removing an impurity and condensing squalene (See paragraph 0010) and that a ketone system, alcoholic system and hydrocarbon system, can be used as an organic solvent, although alcohol is desired (C_1 - C_4), as clearly taught by Hirata.

Moreover, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the referenced method because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose additional or alternative method steps and modify method steps to obtain useful components, such as phytosterols, squalene and vitamin E from palm oil, because at the time the invention was made, methods of obtaining phytosterols, squalene and vitamin E were known in the art and were combinable. Thus, the claimed invention is no more than the routine optimization of a

result effect variable.

The result-effective adjustment of particular conventional working conditions (e.g., adjusting the amount of solvent used to perform an extraction, determining an appropriate type of solvent to use in an extraction, determining the number of times a distillation is repeated and determining the most efficient and highest yielding way to obtain a desired product from palm oil) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
July 5, 2007


MICHELE FLOOD
PRIMARY EXAMINER